

# **Regulatory Data Sheet**

# **DOWLEX™ 2388 Polyethylene Resin**

Information provided in this Regulatory Data Sheet (RDS) does not indicate Dow product availability in all countries aligned with the below regulations. Please contact Dow to confirm availability of product in specific countries.

## **Global Chemical Inventory Compliance**

| Country                        | Inventory | Status   |
|--------------------------------|-----------|--|
| Australia                      | AIIC      | All substances contained in this product are listed on<br>the Australian Inventory of Industrial Chemicals, or are<br>not required to be listed.   |
| Canada                         | DSL       | All substances contained in this product are listed on the Canadian Domestic Substances List (DSL) or are not required to be listed.   |
| China                          | IECSC     | All intentional components are listed on the inventory, are exempt, or are supplier certified.   |
| Japan                          | ENCS      | All intentional components are listed on the inventory, are exempt, or are supplier certified.   |
| Korea                          | KECI      | All intentional components are listed on the inventory, are exempt, or are supplier certified.   |
| New Zealand                    | NZIoC     | There is no requirement to list components of this product on the New Zealand Inventory of Chemicals (NZIoC).  |
| Philippines                    | PICCS     | All intentional components are listed on the inventory, are exempt, or are supplier certified.   |
| Switzerland                    | EINECS    | This product is a polymer according to the definition in Directive 92/32/EEC (7th Amendment to Directive 67/548/EEC) and all of its starting materials and intentional additives are listed in the European Inventory of Existing Commercial Chemical Substances (EINECS) or in compliance with European (EU) chemical inventory requirements. |
| Taiwan                         | TCSI      | All intentional components are either listed on the Inventory or exempted by regulations, or certified by vendors of their supply chemicals.   |
| United States of America (USA) | TSCA      | All components of this product are in compliance with the inventory listing requirements of the U.S. Toxic Substances Control Act (TSCA) Chemical Substance Inventory.   |

## **REACH**

For information on Dow and the European Union regulation for Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), visit our website, https://reach.dow.com/en-us. This product is not manufactured or formulated with any of the Substances of Very High Concern (SVHC) as per the candidate list that was current as of the effective date of this regulatory datasheet that would require reporting under this regulation. Current information can be found at the ECHA website. https://echa.europa.eu/candidate-list-table. Please contact Dow's Customer Information Group for more information (http://www.Dow.com/en-us/contact-us-cig).

# **Food Contact Regulations**

The following status applies when used unmodified and processed in accordance with Good Manufacturing Practices (GMP) for food contact applications.

| Regulation  | Statement  |
|---|--|
| 21CFR177.1520 Olefin polymers   | The composition of this product complies with this regulation with limitation. Paragraph (c)3.2a An additive present in this product limits use in contact with Food Types I, II, IV-B, VI-B, VII-B, and VIII as described in Table1 and Conditions of Use B-H described in Table 2 of U.S. FDA 21 CFR 176.170(c) Not for use in contact with infant formula and human milk. |
| Canadian Food and Drug Regulations, Division 23 Food Packaging Materials  | The composition of this product has not been assessed for this regulation.   |
| Regulation (EU) 10/2011 on plastic materials and articles intended to come into contact with food as amended (latest amendment: Regulation (EU) 2023/1627)                        | The composition of this product complies with this regulation with limitation. Please contact Dow at FGLREGL@dow.com if you require a detailed food contact letter.  |
| Indian Standard IS 10146:1982, Specification for Polyethylene for its safe use in Contact with Foodstuffs, Pharmaceuticals and Drinking Water                                     | The composition of this product complies with this regulation.   |
| Indian Standard IS 16738:2018, Positive List of Constituents for Polypropylene, Polyethylene and their Copolymers for its Safe Use in Contact with Foodstuffs and Pharmaceuticals | The composition of this product complies with this regulation.   |
| GB 4806.1-2016 Food Safety National Standard for<br>General Safety Requirements for Food-Contact<br>Materials and Articles  | The composition of this product complies with this regulation.   |
| GB 4806.7-2023 Food Safety National Standard for Food-contact Use Plastic Materials and Articles  | The composition of this product complies with this regulation with limitation.   |
| GB 9685-2016 Food Safety National Standard of Use of Additives for Food contact Materials and Articles  | The composition of this product complies with this regulation with limitation. Please contact Dow at FGLREGL@dow.com if you require a detailed food contact letter.  |
| MHW Notification Nbr.370 (1959S34), APPENDED  | All intentional substances* in this product are listed   |



| TABLE 1, Japan  | [*in the final FCM UCP (Food Contact Material - Utensil, Container and Package) material]. |
|---|--|
| MERCOSUR - Resolución GMC No. 02/2012 -<br>Monomers, other Starting Substances, and<br>authorized Polymers for Plastic Packaging and<br>Equipment in Food Contact   | The composition of this product complies with this regulation.                             |
| MERCOSUR - Resolución GMC No. 39/2019 -<br>Additives for Plastic Materials and Polymeric<br>Coatings in Food Contact  | The composition of this product complies with this regulation.                             |
| MERCOSUR - Resolución GMC No. 56/1992 -<br>General Provisions for Plastic Packaging and<br>Equipment in Food Contact  | The composition of this product complies with this regulation.                             |
| ANVISA - RDC Resolução No. 052/2010 - Dyes in Plastic Packaging and Equipments intended to come into Contact with Food  | The composition of this product complies with this regulation.                             |
| ANVISA - RDC Resolução No. 056/2012 -<br>Monomers, other Starting Substances, and<br>authorized Polymers for Plastic Packaging and<br>Equipment in Food Contact   | The composition of this product complies with this regulation.                             |
| ANVISA - Resolução No. 105/1999 - General Provisions for Plastic Packaging and Equipments to come into Contact with Food  | The composition of this product complies with this regulation.                             |
| ANVISA - RDC Resolução No. 326/2019 -<br>Additives intended to the production of Plastic<br>Materials and Polymeric Coatings to come into<br>Contact Food   | The composition of this product complies with this regulation.                             |
| INVIMA - Resolución No. 4143/2012 - Plastic and Elastomeric Materials, Objects, Packaging, and Equipments (and their additives) intended to come into Contact with Food and Beverages for human consumption | The composition of this product has not been assessed for this regulation.                 |

Please contact Dow's Customer Information Group if you require further information (https://www.dow.com/en-us/contact-us.html).

It remains the responsibility of the food producer to determine the suitability of the product for the end use and to ensure the legal and regulatory compliance of the product as incorporated into foods. It remains the responsibility of the manufacturer of the material/article which in its finished state is intended for food contact applications to determine the suitability of the product for the end use and to ensure the legal and regulatory compliance of the product as incorporated in the material/article intended for food contact applications, including SMLs, QM and other restrictions/limits under the applicable law/regulations.

### **Pharmaceutical Regulations**

#### U.S. Food & Drug Administration (FDA) Drug Master File

This product is not currently listed under a U.S. FDA Drug Master File (DMF).



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### U.S. Pharmacopoeia (USP)

The composition of this product has not been assessed for this regulation.

### **Dietary Laws**

#### Halal

This product does not contain any substances of animal origin. To the best of our knowledge this product can be used with halal products without compromising the halal status of the products.

#### Kosher

This product does not contain any non-kosher substances. To the best of our knowledge, this product can be used with kosher products without compromising the status of the products.

## Indonesia Halal Positive List (Decree of Minister of Religious Affairs No. 1368/2021)

This product is categorized as a synthetic polymer of polyethylene, which is listed in the Indonesia Halal Positive List. This product is exempted from the Certification requirements of this regulation.

### **Child Safety Regulations**

### Consumer Product Safety Improvement Act of 2008 (CPSIA)

This product is not manufactured or formulated with lead, di-(2-ethylhexyl)phthalate (DEHP), dibutyl phthalate (DBP), or benzyl butyl phthalate (BBP). To the best of our knowledge, it does not contain these materials above the limits set in the Consumer Product Safety Improvement Act of 2008, Title 1, Sections 101 and 108.

### **Toy Safety - ASTM F963 / EN 71-3**

This product is not formulated with antimony, arsenic, barium, boron, cadmium, chromium, cobalt, copper, mercury, lead, nickel, selenium, strontium or tin. To the best of our knowledge, it does not contain these substances above the limits set in ASTM F 963-11, Section 4.3.5.2. This product complies with the requirements of EN 71 Safety of Toys - Part 3, Migration of Certain Elements.

#### **Environment - Air**

### **Clean Air Act**

This product is not manufactured or formulated with Class I or II substances as defined under 40 CFR part 82 of the Clean Air Act of 1990, as amended (58 FR 8136).

## **Hazard Information Reporting (RTK)**

### California Prop. 65



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This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

## **Metal Regulations**

## Conflict Minerals (Dodd-Frank Wall Street Reform and Consumer Protection Act)

This product is not intentionally manufactured or formulated with the listed conflict minerals as per Section 1502 of the Dodd-Frank Wall Street Reform and Consumer Protection Act; however, we do not analyze for these specific substances or compounds.

- Columbite-Tantalite refined into Tantalum (Ta) (CAS # 7440-25-7)
- Cassiterite refined into Tin (Sn) (CAS # 7440-31-5)
- Wolframite refined into Tungsten (W) (CAS # 7440-33-7)
- Gold (Au) (CAS # 7440-57-5)

For more information please visit Dow's Corporate Website - https://corporate.dow.com/en-us/about/codes-of-conduct

## EU 94/62/EC - Packaging and Packaging Waste

This product conforms to the European Directive 94/62/EC, as amended, on Packaging and Packaging Waste, Article 11. Any incidental levels of lead, cadmium, hexavalent chromium, and mercury do not exceed 100 ppm total.

### **Coalition of Northeastern Governors (CONEG)**

This product conforms to the Coalition of Northeastern Governors (CONEG) Toxic in Packaging Legislation. Any incidental levels of lead, cadmium, hexavalent chromium, and mercury do not exceed 100 ppm total.

### **Mineral Oil**

### Mineral Oil Aromatic Hydrocarbons / Mineral Oil Saturated Hydrocarbons

This product is not intentionally formulated with Mineral Oil Aromatic Hydrocarbons (MOAH) or Mineral Oil Saturated Hydrocarbons (MOSH); however, trace amounts (ppm) of food grade, White Mineral Oil (MOSH) in compliance with Commission Regulation (EU) No 10/2011 and U.S. FDA food contact requirements may be present.

### **Origin**

### Animal Derived Components (BSE/TSE)

This product does not contain substances of animal origin, and, to the best of our knowledge, does not come into contact with substances of animal origin during its manufacturing process.

## Palm Oil Derived Components

Palm oil, as such, is not used in the manufacturing of this product; however, palm oil derivatives are used in the manufacturing of one or more raw materials utilized in the production of this product. These palm oil



derivatives are only purchased from suppliers which are members of the "Roundtable on Sustainable Palm Oil" (RSPO).

## **Genetically Modified Organisms (GMO)**

To the best of our knowledge, there are no raw materials, including additives, that have been derived from genetically modified organisms (GMO). This is based on information from our additive suppliers. Therefore, although we believe this product to be GMO free, we cannot guarantee it at this time.

### **Plant Derived Components**

This product may contain one or more substances(s) synthesized from plant extracts, i.e. hydrolysis of plant oils into fatty acids and/or their derivatives, as per information from our raw material suppliers.

### **Waste Regulations**

### EU Directive 2012/19/EU on Waste Electrical and Electronic Equipment (WEEE)

EU Directive 2012/19/EU on WEEE: Selective treatment of the waste (Annex VII). None of the substances listed in Annex VII are intentionally added or used in the formulation of this product with the following exception. This product is a hydrocarbon; however, liquid hydrocarbons are not present in this product.

### **General/Global Regulations**

### Food Allergens

To the best of our knowledge, there are no raw materials, including additives, that have their origin in peanuts, soybeans, milk, eggs, fish, shellfish (mollusks), crustaceans, tree nuts, mustard, celery, sesame, sunflowers, lupine, animal or vegetable proteins, caffeine, monosodium glutamate (MSG), colorants (including carmine and cochineal), corn, wheat, barley, rye, triticale, gluten, mushrooms, yams, and/or phenylalanine and its derivatives. No sulfates, sulfites, or sulfur dioxide are used in the synthesis of this material. This evaluation is based on information provided by our raw material and additive suppliers for the presence of the allergen-stimulating substances shown above. Therefore, although we believe this product to be free of the specified known allergy stimulating food substances, we cannot guarantee this.

### ANVISA/RDC Resolution N° 727

This includes food allergens listed in ANVISA / RDC Resolution No 727 of 07/01/2022. The allergy-stimulating compounds listed herein are not included on the specifications for this product and no specific testing for their presence is performed. Based on the factors listed, this product, when purchased directly from Dow or in Dow factory-packed containers, is believed to be free of all the specified, known allergy-stimulating substances; therefore, batch-specific allergen analysis or certification is not needed.

### Canadian Environmental Protection Act - Challenge Substances

This product is not intentionally manufactured or formulated with the Batch Lists of Canadian Environmental Protection Agency (CEPA) Challenge Substances released as of the effective date of this



document. However, we do not analyze for these specific substances. (http://www.chemicalsubstanceschimiques.gc.ca/challenge-defi/index-eng.php)

## EU Directive 2011/65/EU (RoHS)

This product complies with the requirements of Article 4.1 of EU Directive 2011/65/EU (RoHS 2), as amended (Directive (EU) 2015/863 inclusive) (RoHS 3). It is not intentionally manufactured or formulated with cadmium, hexavalent chromium, lead, mercury, polybrominated biphenyls (PBB), polybrominated diphenyl ethers (PBDE), Bis(2-ethylhexyl) phthalate (DEHP), Butyl benzyl phthalate (BBP), Dibutyl phthalate (DBP), or Diisobutyl phthalate (DIBP).

### **Butylated Hydroxy Toluene (BHT)**

This product is not formulated with Butylated Hydroxytoluene (BHT - CAS # 128-37-0); however, it may contain trace amounts up to a maximum of 5 ppm.

### **Substances and Compounds**

The following substances are not expected to be present in this Product. We may not specifically analyze for the presence of these substances in the Product. Therefore, we cannot guarantee the absence or level of these substances to any specific limit or threshold value:

1,4-Dioxane

2-Isopropylthioxantone (ITX)

Acrylamide

Adipates

Alkyl phenols

Alkylphenol ethoxylates

Antimony (Sb) or antimony compounds

**Aromatic Amines** 

Arsenic (As) or arsenic compounds

Asbestos

Azo compounds

Benzophenones

Beryllium (Be) or beryllium compounds

**Biocides** 

Bis(2-ethylhexyl) adipate (DEHA)

Bisphenol A

Bisphenol A-diglycidylether (BADGE)

Bisphenol B (BPB) (77-40-7)

Bisphenol C (BPC) CAS# 79-97-0

Bisphenol E (BPE) (2081-08-5)

Bisphenol F

Bisphenol F diglycidyl ether (BFDGE)

Bisphenol S (BPS) (CAS No. 80-09-1)

Bisphenol Z (BPZ)(843-55-0)

Butylated Hydroxy Anisole (BHA)

Cadmium (Cd) or cadmium compounds

Chlorinated paraffins



Chlorofluorocarbons (CFCs) or Hydrochlorofluorocarbons (HCFCs)

Colophonium / Gum rosin / Rosin

Colorants or pigments

Copper (Cu) or copper compounds

**Dimethyl Fumarate** 

Dioxins

Dry Natural Rubber (DNR)

**Endocrine Disrupting Substances** 

**Fiberglass** 

Flavorings

Fluorescent whitening agents

Fluorotelomer

Formaldehyde

Fragrances

Fungicides

**Furans** 

Halogenated Flame Retardants

Hexachlorobenzene

Human origin

Jatropha Plant (Derivatives or parts)

Latex

Lead/Lead Compounds

Melamine

Mercury (Hg) or mercury compounds

**Nanomaterials** 

Natural Rubber Latex (NRL)

Nickel (Ni) or nickel compounds

Nonylphenol

Nonylphenol ethoxylates

Novolac Glycidyl Ether (NOGE)

Organic nitro- or nitroso- containing substances

Organo-Tin Compounds

Ozone Depleting Substances

Parabens

Pentachlorophenol

Perchlorates

Perfluoroalkyls (PFAS)

Perfluorooctane sulfonate (PFOS)

Perfluorooctanoic acid (PFOA)

**Pesticides** 

Phthalate esters

**Phthalates** 

**Plasticizers** 

Polybrominated Biphenyls (PBB)

Polybrominated Diphenyl ether (PBDE)

Polybrominated Terphenyls (PBT)

Polychlorinated and Polybrominated Naphthalenes

Polychlorinated Biphenyls (PCB)

Polychlorinated Terphenyls (PCT)



22.11.2023

Polycyclic Aromatic Hydrocarbons (PAHs) Polyfluoroalkyls (PFAS) Polyvinyl Chloride (PVC) Polyvinylidenechloride (PVDC) Radioactive substances Recycled materials Silicone / Surface active substances Silver (Ag) or silver compounds Styrene Synthetic Latex Tertiary butylhydroguinone (TBHQ) Triclosan Tris(2-chloroethyl)phosphate (TCEP) Tris(nonylphenyl)phosphite (TNPP) Vinyl chloride (Chloroethylene) **Xylene** 

### **Product Specification**

Zinc (Zn) or zinc compounds

For product specifications, please request a Sales Spec document for this product from The Dow Customer Information Group at http://www.dow.com/en-us/contact-us-cig.

### **Composition Statement**

For information on the components of our product and their concentration, please refer to the Safety Data Sheet (SDS) and the Sales Specification. Any hazardous constituents above regulatory disclosure cut-off limits determined according to their regional and/or specific GHS classification(s) will appear in the ingredients section of the SDS. In addition, consult the Hazardous Decomposition Products section for further information. You can search https://www.dow.com/en-us/support/sds-finder.html for an available SDS.

#### **Responsible Care**

Dow complies with the American Chemistry Council's Responsible Care® guiding principles, codes, and management system requirements. Dow has recommitted its support for Responsible Care on a global scale by signing the Responsible Care Global Charter under the auspices of the International Council of Chemical Associations (ICCA). Dow has also endorsed the ICCA's Global Product Strategy, an effort by the global chemical industry to further improve its product stewardship efforts. Our EH&S management system is audited regularly to ensure compliance with all applicable governmental requirements, Responsible Care, and internal Dow requirements.

Dow has adopted what we call our "2025 Sustainability Goals" -- ambitious performance improvement goals with a broad external focus: strengthening our relationships with the communities where we operate, continuing to improve our product stewardship and innovation, and reducing our global footprint. In support of these goals, Dow is constantly working to improve our performance through focused EH&S programs such as the Waste Reduction Always Pays (WRAP) program. More information can be found by visiting https://www.dow.com/en-us.html.



#### **Product Stewardship**

Dow has a fundamental concern for all who make, distribute, and use its products, and for the environment in which we live. This concern is the basis for our product stewardship philosophy by which we assess the safety, health, and environmental information on our products and then take appropriate steps to protect employee and public health and our environment. The success of our product stewardship program rests with each and every individual involved with Dow products - from the initial concept and research, to manufacture, use, sale, disposal, and recycle of each product.

#### **Customer Notice**

Dow strongly encourages its customers to review both their manufacturing processes and their applications of Dow products from the standpoint of human health and environmental quality to ensure that Dow products are not used in ways for which they are not intended or tested. Dow personnel are available to answer your questions and to provide reasonable technical support. Dow product literature, including safety data sheets, should be consulted prior to use of Dow products. Current safety data sheets are available from Dow.

### **Medical Applications Policy**

NOTICE REGARDING MEDICAL APPLICATION RESTRICTIONS: Dow does not support or intend for its products to be used in: a. long-term or permanent contact with internal bodily fluids or tissues. "Long-term" is contact which exceeds 29 calendar days; b. use in cardiac prosthetic devices regardless of the length of time involved ("cardiac prosthetic devices" include, but are not limited to, pacemaker leads and devices, artificial hearts, heart valves, intra-aortic balloons and control systems, and ventricular bypassassisted devices):

- c. use as a critical component in medical devices that support or sustain human life; or
- d. use specifically by pregnant women or in applications designed specifically to promote or interfere with human reproduction.
- e. use as an ingredient of a pharmaceutical injectable application.

Dow requests that customers considering use of Dow products in medical applications notify Dow so that appropriate assessments may be conducted. Dow does not endorse or claim suitability of its products for specific medical applications. It is the responsibility of the medical device or pharmaceutical manufacturer to determine that the Dow product is safe, lawful, and technically suitable for the intended use. DOW MAKES NO WARRANTIES, EXPRESS OR IMPLIED, CONCERNING THE SUITABILITY OF ANY DOW PRODUCT FOR USE IN MEDICAL APPLICATIONS.

### **Tobacco and Marijuana Policy**

Dow does not support or intend for its products to be used, directly or indirectly, in the production of tobacco, the manufacture of tobacco products, the manufacture and use of electronic cigarettes/vaping, the production of marijuana, or the manufacture of marijuana products intended for human consumption, where the Dow product (or its residues) may be present in the finished product or be alleged to facilitate the delivery of nicotine, other tobacco components, marijuana, or marijuana components.

#### **Harmful Applications Policy**

Dow does not intend for its products to be used in applications specifically intended to harm humans.

#### Disclaimer

NOTICE: No freedom from infringement of any patent owned by Dow or others is to be inferred. Because use conditions and applicablelaws may differ from one location to another and may change with time, Customer is responsible for determining whether products and the information in this document are appropriate for Customer's use and for ensuring that Customer's workplace and disposal practices are in compliance with applicable laws and other government enactments. The product shown in this literature may not be available for sale and/or available in all geographies where Dow is represented. The claims made may not have been approved for use in all countries. Dow assumes no obligation or liability for the information in this document. References to "Dow" or the "Company" mean the Dow legal entity selling the products to Customer unless otherwise expressly noted. NO WARRANTIES ARE GIVEN: ALL IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE ARE EXPRESSLY EXCLUDED. NO WARRANTIES ARE GIVEN; ALL IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE ARE EXPRESSLY EXCLUDED.

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